UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/036,569	06/11/98	SCHNEIDER	

020583
PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK NY 10036-2711

HM11/0509

EXAMINER	
PEGUIT, R	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 05/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/096,589	Schneider et al.
Examiner	**Art Unit**
Rebecca Prouty	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 22, 2000*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *39-42, 45, and 46* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *39-42, 45, and 46* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Claims 1-38, 43 and 45 have been canceled. Claims 39-42 and 46 are at issue and are present for examination.

Applicant's election without traverse of Group II of the previous restriction requirement in Paper No. 9 is acknowledged. Applicants cancellation of all claims corresponding to elected Group II was again non-responsive. Applicants argument that the current claims fall into Group II as Group II encompasses use of all Src kinase inhibitors is not agreed with as Group II was intended to encompass use of Src **kinase** inhibitors, i.e., inhibitors of Src enzymatic activity. Inhibitors of upstream activators of Src kinases within the signal transduction pathway of a cell will not have any effect on Src kinase enzymatic activity if incubated together with the kinase. However as all the current claims fall into a single patentably distinct group from all of the previously defined groups, in the interest of advancing prosecution, the current claims have been examined. However, applicant should note that if any claims are presented which would fall in previous Group II, i.e., use of inhibitors of Src enzymatic activity, they will be held withdrawn as patentably distinct from the invention constructively elected for prosecution by original presentation. It should also be noted that the current claims are distinct from previously defined

Groups V-VII which the examiner previously stated (in the non-responsive notice mailed 5-24-00) they appeared to be generic to as the current claims recite use of inhibitors of upstream activators of Src kinases while each of Groups V-VII recite use of inhibitors of distinct downstream effectors of Src kinase activation. As such each of Groups II, V-VII and the current claims all recite use of inhibitors of distinctly different proteins, i.e., Group II= inhibitors of Src kinase, Group V= inhibitors of Ras, Group VI= inhibitors of MAPK, Group VII= inhibitors of Myc and the current claims= inhibitors of upstream activators.

Claim 42 is objected to because of the following informalities: "which" should be "wherein". Appropriate correction is required.

Claims 40-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "the viral protein" in Claim 40 lacks prior antecedent basis.

Claims 41 and 42 are incomplete as depending from canceled claims. Claim 41 has been examined as if dependent only from

Claim 39 and Claim 42 has been examined as if it depended from Claim 39.

Claims 39-42, 45 and 46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to methods of inhibiting HBV infection or replication by administering a compound that interferes with the interactions of HBV proteins with cellular proteins that serve as upstream activators of Src kinases. The specification fails to describe in any fashion the physical and/or chemical properties or any identifying characteristics or properties other than the functionality of interfering with the interactions of HBV proteins with cellular proteins that serve as upstream activators of Src kinases of the claimed class of substances and fails to identify even a single representative species of such compounds. Moreover, the specification fails to describe even a single cellular protein that interacts with any HBV protein, particularly with HBX, and serves as an upstream activator of Src kinases such that the ordinary skilled artisan could not even use standard screening methods to find compounds

within the claimed class. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 39-42, 45 and 46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims broadly recite the use of **any** substance that interferes with the interaction of any HBV protein with cellular proteins that serve as upstream activators of Src kinases to inhibit HBV infection or replication. The specification fails to describe in any fashion the physical and/or chemical properties or any identifying characteristics or properties other than the functionality of interfering with the interactions of HBV proteins with cellular proteins that serve as upstream activators of Src kinases of the claimed class of substances and fails to identify even a single such compound. Moreover, the specification fails to describe even a single cellular protein

that interacts with any HBV protein, particularly with HBX, and serves as an upstream activator of Src kinases such that the ordinary skilled artisan could not even use standard screening methods to find compounds within the claimed class. While the prior art teaches a number of upstream activators of Src kinases (growth factor receptors, the ligands which activate these receptors, and receptor protein tyrosine phosphatase α) none of these has been shown to interact with any HBV protein, including HBX in particular. Without some showing how HBX (or another HBV protein) activates Src kinases *in vivo* one of ordinary skill in the art would have no reasonable expectation that inhibiting one or more upstream activators of Src kinases would have any effect of HBV infection and/or replication. Furthermore, the screening methods recited in Claims 45 and 46 (which test the effect of a compound on the activity of a component of the upstream activation pathway of Src) would not lead one of ordinary skill in the art to compounds which interfere with interactions between a HBV protein and a cellular protein that serves as a upstream activator of Src kinase unless the component of the upstream activation pathway of Src used in the assay interacts with an HBV protein. Even further, it should be noted that merely the presence of an interaction between an HBV protein and a cellular

protein is insufficient for one of ordinary skill in the art to conclude that the interaction is important for initiating and/or maintaining HBV infection. While the specification suggests that HBX mediated induction of Src kinase is necessary for initiating and/or maintaining HBV infection, neither the specification not the art provides any teaching of the mechanism by which HBX activates Src and known of the known activities of the HBX protein suggest any particular method of Src activation. As such practice of the claimed methods would require undue experimention to find and make compounds with the claimed activities.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Rebecca Prouty
Primary Examiner
Art Unit 1652